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Atty. Dkt. No. 029488-0112

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Jay BUA  
Title: REDUCTION OF BREAST DENSITY WITH 4-HYDROXY  
TAMOXIFEN  
Appl. No.: 10/734,644  
Filing Date: 12/15/2003  
Examiner: Not yet assigned  
Art Unit: 1645

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding International application. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner. An English-language counterpart of the foreign-language documents has not been provided. The absence of a translation or an English-language counterpart document does not relieve the PTO from its duty to consider any submitted document (37 CFR §1.98 and MPEP§609).

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.


Respectfully submitted,

Date

10/4/04

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By

  
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<b>Substitute for form 1449B/PTO</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>  Date Submitted: October 4, 2004 <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				<b>Application Number</b>	10/734,644
				<b>Filing Date</b>	12/15/2003
				<b>First Named Inventor</b>	Jay BUA
				<b>Group Art Unit</b>	1645
				<b>Examiner Name</b>	Not yet assigned
				<b>Attorney Docket Number</b>	029488-0112
<b>Sheet</b>	1	<b>of</b>	1		

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B1		WO 85/03228		Pierre MAUVAIS JARVIS et al.	8/1/1985		
	B2		WO 95/24187		Hexal-Pharma GMBH	9/14/1995		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>6</sup>
	B3	International Search Report		
	B4	Pierre MAUVAIS-JARVIS et al., "trans-4-Hydroxytamoxifen Concentration and Metabolism after Local Percutaneous Administration to Human Breast", Cancer Research Vol. 46, March 1986, pp. 1521-1525.		
	B5	F. KUTTENN et al., "Principe de l'administration percutanée des antiestrogènes en pathologie mammaire", Contracept. Fertil. Sex., 1991, Vol. 19, No. 2, pp. 165-171.		
	B6	Catherine MALET et al., "Effect of 4-hydroxytamoxifen isomers on growth and ultrastructural aspects of normal human breast epithelial (HBE) cells in culture", Journal of Steroid Biochemistry and Molecular Biology 82, (2002), pp. 289-296.		
	B7	Charlotte ATKINSON et al., "Mammographic Patterns as a Predictive Biomarker of Breast Cancer Risk: Effect of Tamoxifen", Cancer Epidemiology, Biomarkers and Prevention Vol. 8, October 1999, pp. 863-866.		

<b>Examiner Signature</b>		<b>Date Considered</b>	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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